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REVISED DRAFT BASELINE ECOLOGICAL RISK ASSESSMENT WORK PLAN FOR POLYCHLORINATED DIBENZO-*p*-DIOXINS (PCDDS) AND DIBENZOFURANS (PCDFS) IN THE TITTABAWASSEE RIVER AND ASSOCIATED FLOODPLAINS

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Definitions and Acronyms

AhR	Aryl hydrocarbon receptor
ADDpot	Average potential daily dose
ATL	Aquatic Toxicology Laboratory
BERA	Baseline ecological risk assessment
COPECs	Chemicals of potential ecological concern
DDT	Dichlorodiphenyltrichloroethane
DQOs	Data quality objectives
EEC	Estimated exposure concentration
EPC	Exposure point concentration
ERA	Ecological risk assessment
FSP	Field sampling plan
GBH	Great blue heron
HQ	Hazard quotient
ID	Identification
LCS	Laboratory control spike
LCSD	Laboratory control spike duplicate
LOAEL	Lowest observable adverse effect level
LOD	Limit of detection
MATC	Maximum allowable tissue concentration
MDCH	Michigan Department of Community Health
MDEQ	Michigan Department of Environmental Quality
MDL	Method detection limit
MDNR	Michigan Department of Natural Resources
MS	Matrix spike
MSD	Matrix spike duplicate
MSU	Michigan State University
NFSTC	National Food Safety and Toxicology Center
NOAEL	No observable adverse effect level
PCBs	Polychlorinated biphenyls

PCDDs	Polychlorinated dibenzo-*p*-dioxins
PCDFs	Polychlorinated dibenzofurans
QAPP	Quality assurance project plan
QA	Quality assurance
QC	Quality control
RPD	Relative percent difference
RPF	Relative potency factor
RI	Remedial investigation
ROC	Receptor of concern
RSD	Relative standard deviation
S-HASP	Site specific health and safety plan
SLERA	Screening level ecological risk assessment
SMDP	Scientific management decision points
SOP	Standard operating procedure
SPMD	Semi permeable membrane device
SRM	Standard reference material
SSL	Soil screening levels
TEFs	Toxic equivalency factors
TEQs	TCDD equivalents
TFV	Toxicity reference values
TCDD	2,3,7,8-Tetrachlorodibenzo-*p*-dioxin
TRV	Toxicity reference value
UCL	Upper confidence limit
UF	Uncertainty factor
URCF	University Research and Containment Facility
USEPA	United States Environmental Protection Agency
USFWS	United States Fish and Wildlife Service
WHO	World Health Organization

1.0 INTRODUCTION

The Tittabawassee River study area, hereafter referred to as the "Site", includes sediments and floodplain soils for approximately 23 miles of the Tittabawassee River downstream of Midland, Michigan. Specifically, the Site includes the Tittabawassee River from the upstream boundary of The Dow Chemical Company to the confluence of the Tittabawassee and Shiawassee Rivers downstream of Greenpoint Island, as defined in the Hazardous Waste Management Facility Operating License, which was issued on June 12, 2003 by Michigan Department of Environmental Quality (MDEQ) to The Dow Chemical Company (Dow). This baseline ecological risk assessment (BERA) workplan is designed to satisfy the requirements under the Operating License to conduct an ecological risk assessment (ERA) as part of the Remedial Investigation (RI) process, specifically Condition XI.B.3.v of the Operating License.

Based on historical data, it is assumed that polychlorinated dibenzo-*p*-dioxins (PCDDs) and dibenzofurans (PCDFs) will continue to be chemicals of potential ecological concern (COPECs) and are thus the main focus of this BERA workplan. Previous documents have reported concentrations of PCDDs and PCDFs in the sediments, floodplain soils, and fish of the Tittabawassee Rivers that exceed some state generic criteria (MDEQ, 2002; Hilscherova et al., 2003; MDEQ, 2003). Currently, there is insufficient information on the presence or concentration of PCDDs and PCDFs in the tissues or diets of avian and mammalian wildlife species that reside within the study or reference areas to accurately ascertain the risks these chemicals may pose to wildlife utilizing the Tittabawassee River and its floodplain. In addition, there is very little information on the population health of key species in the study area. A search of the published scientific literature revealed that available models are fraught with uncertainty and are typically site-specific. As recognized by the USEPA (USEPA, 1997; USEPA 1998), site-specific field studies are almost always required for sound decision making. This is especially true for complex systems such as the Tittabawassee River. As a result, this BERA Work Plan is designed to provide a survey of species-specific dietary exposure concentrations and tissue residue concentrations in wildlife that are potentially exposed to PCDDs and PCDFs in the Tittabawassee River and floodplain soils. Several studies are described in this Work Plan to address data gaps and reduce uncertainty in the risk assessment process.

1.1 Purpose and Scope

The overall purpose of this Work Plan is to present a detailed approach for conducting a BERA for the Tittabawassee River and associated floodplain. More specifically, this Work Plan outlines a framework for evaluating relevant lines of evidence and identifies key data that need to be collected in order to evaluate risks to key ecological receptors in the Site from exposure to COPECs. The primary COPECs addressed in the BERA, based on historical knowledge of the site, are PCDDs and PCDFs. However, the iterative nature of the BERA process will accommodate any additional COPECs that are identified in the screening level ecological risk assessment (SLERA). The SLERA process is covered in detail in a separate SLERA Work Plan (ENTRIX 2005). The results from this BERA will be used to:

- Determine the dietary composition of key receptors and the concentrations of PCDDs and PCDFs in site-specific and receptor-specific dietary items;
- Compare dietary exposure concentrations to literature-based TRVs;
- Determine how tissue residue concentrations from the site compare to similar samples collected from reference areas, and how those concentrations compare to literature-based toxicity reference values (TRVs);
- Provide information necessary to identify and quantify the risks to wildlife populations from contaminants found at the site so that appropriate actions can be taken;

- Inform the public and other interested stakeholders of concentrations of PCDDs and PCDFs and total TEQs (based on PCDDs and PCDFs as described later) in selected tissues of food web items and wildlife species collected from the Tittabawassee River and floodplain;
- Perform exposure pathway analyses for receptors of concern to provide the information necessary to mitigate exposure;
- Satisfy the RI requirement (Rule 299.5528(3)(m)) to consider natural resource injury evaluation; and
- Evaluate the need for further study or risk mitigation for the protection of ecological receptors.

Included in this BERA Work Plan are site-specific studies to be performed by Michigan State University's (MSU) Aquatic Toxicology Laboratory (ATL). In 2003 and 2004, The Dow Chemical Company provided grants to the MSU ATL to conduct ecological studies along the Tittabawassee River and associated floodplains (MSU, 2003). These studies will focus on PCDD and PCDF accumulation into terrestrial and aquatic food webs and also focus on measures of population and reproductive health of key receptors. Anticipated data availability from the MSU-ATL studies is presented in Table 1-1 for each of three lines of evidence. All relevant and available data will be evaluated for quality and usefulness in the BERA.

Table 1-1. Anticipated availability of datasets from MSU-ATL studies.

Receptor	Dietary-based exposure analysis	Receptor tissue concentrations	Productivity measurements
Shrew	2006	2006	ND
Mink	2006	2006	2007
Tree swallow	2006	2007	2008
Eastern bluebird	2006	2007	2008
House wren	2006	2007	2008
American robin	2006	2007	ND
Great horned owl	2006	2007	2008
Great blue heron	2006	2008	2008
Belted kingfisher	2006	2007	2008

"ND" – no data are being collected on this topic
Details of the MSU ATL studies are presented in Appendices C through G.
Some portions of datasets may be available prior to completion.

1.2 Regulatory Guidance and Outline of Proposed Approach

This BERA Work Plan is based upon USEPA ERA guidance (Figure 1-1; USEPA 1997; USEPA 1998; USEPA 1999; USEPA 2001a and b), applicable state regulatory guidance including Part 201 of Act 451, and the conditions of the Operating License. In addition, this Work Plan considered the recent "Draft Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment" (USEPA, 2003a).

The general proposed approach for this ERA follows the USEPA ERA guidance for Superfund (USEPA, 1997). The eight step process within the USEPA ERA guidance for Superfund sites is designed to focus resources on key chemicals, pathways of exposure, and receptors and to eliminate from further consideration those chemicals, pathways, and receptors that are clearly not at risk (Figure 1-1). The approach for this BERA will include the following processes and data collections:

- **Pre-ERA Planning**
  - Planning meetings with MDEQ, USEPA, USFWS, MSU, Dow, and other potential stakeholders
  - Development of preliminary data quality objectives (DQOs)
- **Screening-Level ERA (Described in detail in the Screening-Level ERA Work Plan)**
  - Site visit - including site-specific biota inventory and habitat suitability characterization for the aquatic and terrestrial resources along the Tittabawassee River
  - Compilation of existing information on the COPECs and receptor species at the site
  - Screening-level problem formulation, exposure estimation, and risk characterization
- **Baseline ERA Problem Formulation**
  - Integrate available information to identify exposure pathways and COPECs that will be evaluated in the BERA
  - Selection of assessment endpoints
  - Development of a conceptual site model
  - Development of risk questions and hypotheses
- **Baseline ERA Study Design Phase**
  - Development of data quality objectives (DQOs) for the ERA
  - Selection of measurement endpoints
  - Development of sampling and analysis plans
- **Baseline ERA Analysis Phase – Exposure Assessment**
  - Determine site use and exposure pathways for key receptors or appropriate surrogates
  - Determine concentrations of PCDDs and PCDFs in the aquatic and terrestrial food webs
  - Assess site-specific bioavailability of PCDDs and PCDFs from soils and sediments
  - Estimate potential dietary exposures of receptors to PCDDs and PCDFs
  - Determine concentrations of PCDDs and PCDFs in key receptor tissues
  - Determine the extent to which selected receptor species may be exposed to other COPECs
- **Baseline ERA Analysis Phase – Effects Assessment**
  - Review literature for dietary-based and tissue-based effect levels
- **Risk Characterization**
  - Characterize potential ecological risks using dietary-based exposure assessment

1.3 Schedule

Several major elements, proposed sequencing, and estimated timelines for activities related to conducting a BERA for the Tittabawassee River and floodplain (Figure 1-1) were identified. The planning and exposure analysis phases of the ERA will be coordinated with other elements of the RI to the extent possible, such that information can be appropriately integrated and the RI process can proceed. The duration of the screening-level ERA, baseline ERA problem formulation, baseline ERA study design, and baseline ERA exposure assessment phases will be approximately two years from the date of work plan approval. Most of the data pertaining to the exposure assessment phase will be available as input to focus the ecological effects assessment phase for key ecological receptors for decision making. For the BERA activities, bimonthly progress updates will be provided to MDEQ. For a more detailed discussion of the BERA schedule and proposed BERA reports, refer to section 7.0.

1.4 Work Plan Organization

The remainder of this BERA Work Plan is organized into the following sections and appendices:

Section 2.0. Screening-Level ERA

This section describes how the results of the SLERA will be integrated in the BERA process. For more details, refer to the Draft SLERA workplan (ENTRIX 2005).

Section 3.0. Baseline ERA Problem Formulation Phase

This section provides details concerning selection of assessment endpoints and development of a conceptual site model.

Section 4.0. Baseline ERA Study Design Phase

This section provides information on the overall study design including a description of the data quality objective process, analytical methodology, and data analysis and interpretation.

Section 5.0. Baseline ERA Analysis Phase – Exposure and Effects Assessment

This section provides details concerning the various approaches that will be utilized to determine exposure and effects on ecological receptors of concern and will discuss the uncertainties associated with each approach.

Section 6.0. Baseline ERA Risk Characterization Phase

This section provides details concerning the risk characterization process for each ecological receptor.

Section 7.0. Schedule and Reporting

This section provides an overview of the project schedule.

Section 8.0. References

Appendix A. Quality Assurance Project Plan (QAPP)

The QAPP provides the details governing the quality assurance (QA) and quality control (QC) procedures that will be followed in conducting the studies. It also describes the specific protocols concerning sample acquisition, handling and storage, chains-of-custody, and laboratory analysis.

Appendix B. Site Specific Health and Safety Plan (S-HASP)

A site-specific health and safety plan (S-HASP) will be developed before implementing work described in the BERA Work Plan. This plan clearly states the relevant health and safety requirements for individuals working during this investigation.

Appendices C - G. Baseline ERA Study Plans

These appendices provide data quality objectives for each of the studies and includes details concerning the chemical, physical, and biological measurements that will be made while conducting the studies described.

Appendix H. Standard Operating Procedures (SOPs)

The Standard Operating Procedures provide specific instructions for the procedures that will be followed in the field and laboratory.

Appendix I. Permits in support of MSU study plans

The MSU study plans require numerous university, state, and federal permits to conduct the research appropriately.

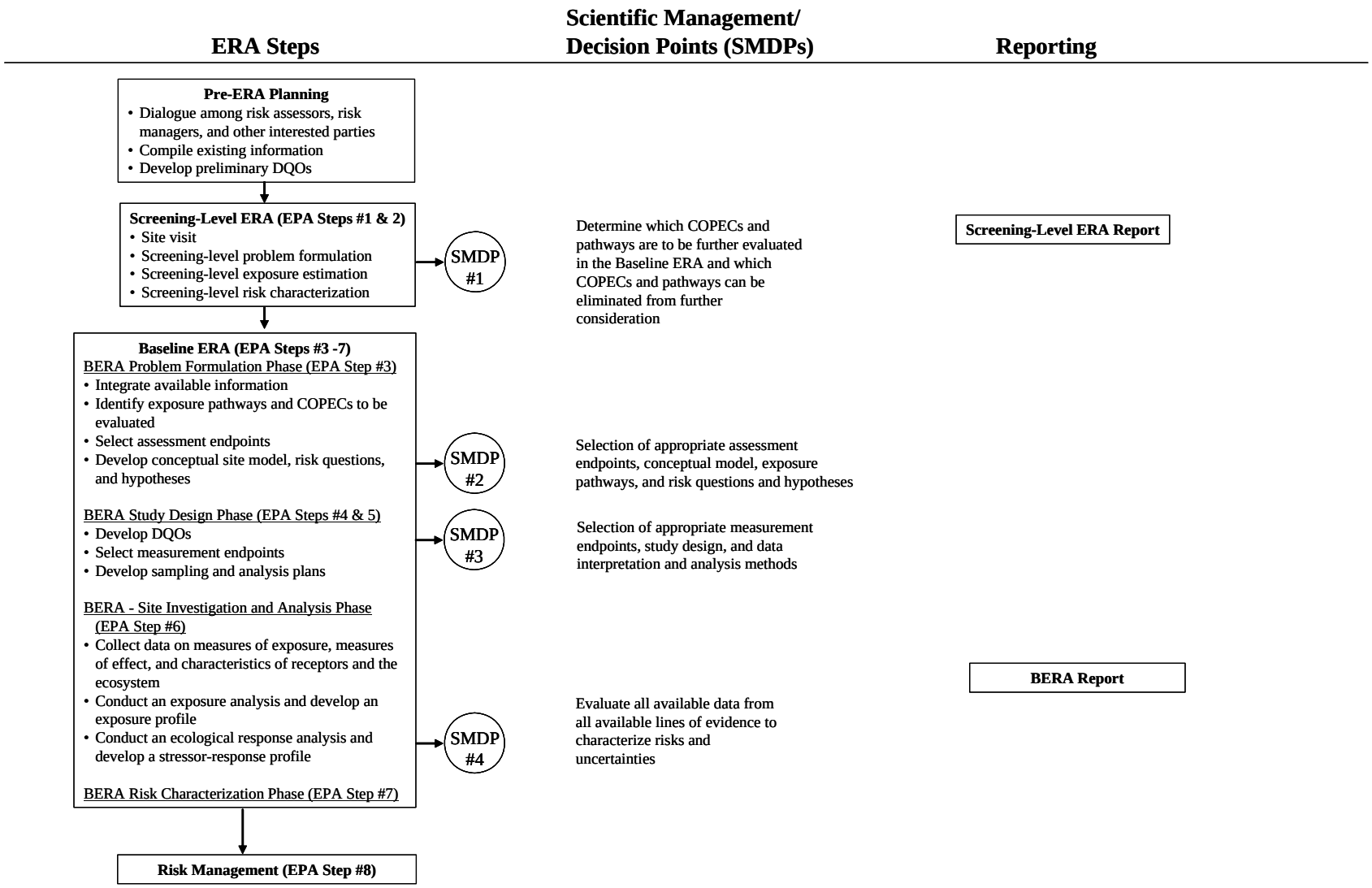

Figure 1-1. ERA steps, scientific management decision points and reporting (based on Superfund ERA Guidance; USEPA, 1997)

2.0 SCREENING-LEVEL ERA (SLERA)

2.1 Introduction

As specified by USEPA guidance, the first step in the ERA process is a screening-level (SLERA) or Tier I ERA in which the objective is to identify and document conditions that do *not* warrant further evaluation in a more refined baseline ERA (BERA). As defined by the USEPA, a SLERA is a simplified risk assessment that can be conducted with limited data where site-specific information is lacking and assumed values are used to evaluate potential exposure and effects (USEPA 1997). For a SLERA, it is important to minimize the chances of concluding that there is no risk when in fact a risk exists, i.e., the technique assures that β is minimized and the probability of a Type II error (false negative) is very low. Thus, for exposure and toxicity or effect parameters for which site-specific information is minimal, assumed values, such as area-use and bioavailability, should be consistently biased in the direction of overestimating risk. This ensures that sites that might pose an ecological risk are studied further, i.e., a SLERA is deliberately designed to be protective in nature, not predictive of effects. If any potentially significant exposure pathways are indicated from the SLERA, then these pathways are further evaluated in a more refined BERA.

2.2 Scientific Management Decision Point #1

Following the SLERA, decisions will be made in consultation with MDEQ regarding the determination of potential ecological risks. These decisions will be made in consultation with the MDEQ and other appropriate stakeholders. Three possible decisions can be reached following the SLERA:

- There is enough information to conclude that ecological risks are low or non-existent and there is no need to clean up the site on the basis of ecological risk; or
- There is not enough information to make a decision and the ERA will proceed; or
- The information indicates a potential for adverse ecological effects, and a higher tiered BERA is required.

The details of the SLERA procedures are presented separately in the SLERA Work Plan (ENTRIX 2005). At the first SMDP COPECs can only be screened out or retained for further assessment. No decisions can be made regarding risk or injuries, and no decisions can be made regarding remedial action. Based on historical data, it is assumed that PCDDs and dibenzofurans PCDFs will continue to be COPECs and are thus the focus of BERA studies presented herein. The conclusions of the SLERA will be used to evaluate which chemicals, in addition to PCDDs and PCDFs should be carried through to the BERA as COPECs. If additional COPECs are identified, the potential ecological risks associated with each COPEC will be further evaluated and characterized as part of the BERA.

3.0 BASELINE ERA PROBLEM FORMULATION PHASE

3.1 Introduction

The problem formulation phase of a BERA provides a framework for a higher tiered risk assessment (USEPA 1992; USEPA 1997; USEPA 1998) in which ecological endpoints are identified and relevant features of the environment and sources of contamination are described. This process includes a description of fate and transport characteristics of the COPECs, a brief evaluation of the potential toxicological effects of the COPECs, an identification of exposure pathways and receptors, the development of a conceptual site model, and the identification of assessment endpoints. Assessment endpoints that are clear, specific expressions of the actual value that is to be protected are the ultimate focus in risk characterization, and act as a link to the risk management process (such as the policy goals).

3.2 Fate and Transport Characteristics of COPECs, and Potential Ecological Effects

Due to historical inputs to the Site, the screening-level evaluation described in the previous section is important in the selection of COPECs. This section describes the characteristics and toxic effects of COPECs known at the time of development of this BERA Work Plan.

3.2.1 Polychlorinated Dibenzo-*p*-Dioxin (PCDD) and Dibenzofuran (PCDF) Congeners

In one study, concentrations of PCDDs and PCDFs were measured in sediments and floodplain soils collected along the Tittabawassee River (Hilscherova et al., 2003). Additionally, concentrations of PCDDs and PCDFs have been measured in several fish species inhabiting the Tittabawassee River, and an initial risk assessment based on these measurements predicted risk to piscivorous avian and mammalian species (GES, 2003).

There are 75 PCDD congeners and 135 PCDF congeners that vary in the degree and position of chlorine substitution. Despite their structural relatedness, each of these congeners has different physico-chemical properties that affect their fate, transport, and bioavailability in the environment. In general, many PCDD and PCDF congeners in the environment are predominantly associated with particulate material, such as sediments, suspended material, and soils. Of the 210 PCDD and PCDF congeners, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD, also referred to as TCDD) is considered to be the most potent and is the one most studied. For example, the potency of TCDD and related compounds in avian and mammalian wildlife has been evaluated in laboratory and field studies (Murray et al., 1979; Gilbertson et al., 1991; Giesy et al., 1994a and 1994b; Ludwig et al., 1996; Powell et al., 1997). Observed effects of TCDD and related chemicals in wildlife and laboratory animals include biochemical adaptive changes such as enzyme induction, developmental deformities, reproductive failure, liver damage, wasting syndrome, and death. The mechanism of action of TCDD and related compounds at the cellular level is primarily mediated through the aryl hydrocarbon receptor (AhR). Because of this assumed similarity in the mechanism of action, concentrations of 17 PCDD and PCDF congeners substituted with chlorines at positions 2, 3, 7, and 8 are routinely converted to TCDD equivalents (TEQs) using the 1998 World Health Organization (WHO) toxic equivalency factors (TEFs), (Table 3-1, Van den Berg et al., 1998) (Equation 3-1). WHO TEF values are not precise measures of relative potencies for PCDD and PCDF congeners. Rather, they are half-order of magnitude, conservative estimates of relative potency across a taxonomic class. As such, they are uncertain and may vary by species and endpoint. Thus, relative potency factors (RPFs) from the scientific literature may be used in place of WHO TEFs in instances where related or same species data are available in order to reduce uncertainty (USEPA, 2003a).

$$TEQ = \sum_{i \to n}[(Congener_i \times TEF_i) + ...(Congener_n \times TEF_n)] \qquad \textbf{Eq. 3-1}$$

Table 3-1. Mammal, fish, and bird-specific toxic equivalency factors (TEFs) from the World Health Organization (WHO) for the 2,3,7,8-chlorine substituted PCDD and PCDF congeners.

	WHO 1998 TEF Values		
	Mammals/ Humans	**Fish**	**Birds**
Polychlorinated dibenzo-*p*-dioxins			
2,3,7,8-TCDD	1	1	1
1,2,3,7,8-PeCDD	1	1	1
1,2,3,4,7,8-HxCDD	0.1	0.5	0.05
1,2,3,6,7,8-HxCDD	0.1	0.01	0.01
1,2,3,7,8,9-HxCDD	0.1	0.01	0.1
1,2,3,4,6,7,8-HpCDD	0.01	0.001	< 0.001
OCDD	0.0001	< 0.0001	0.0001
Polychlorinated dibenzofurans			
2,3,7,8-TCDF	0.1	0.05	1
1,2,3,7,8-PeCDF	0.05	0.05	0.1
2,3,4,7,8-PeCDF	0.5	0.5	1
1,2,3,4,7,8-HxCDF	0.1	0.1	0.1
1,2,3,6,7,8-HxCDF	0.1	0.1	0.1
1,2,3,7,8,9-HxCDF	0.1	0.1	0.1
2,3,4,6,7,8-HxCDF	0.1	0.1	0.1
1,2,3,4,6,7,8-HpCDF	0.01	0.01	0.01
1,2,3,4,7,8,9-HpCDF	0.01	0.01	0.01
OCDF	0.0001	< 0.0001	0.0001

Source: Van den Berg et al., 1998

3.2.2 Polychlorinated Biphenyls (PCBs)

Polychlorinated biphenyls (PCBs) have been measured at detectable concentrations in the Saginaw River and Saginaw Bay downstream from the Tittabawassee River (Froese et al., 1998; Giesy et al., 1997; Verbrugge et al., 1995; Ludwig et al., 1993). However, concentrations of PCBs in soil and sediments along the Tittabawassee River have been determined to be generally low (<0.150 mg/kg, dry wt; Hilscherova et. al. 2003).

PCBs are a family of 209 chemicals, which differ in the number and position of chlorine atom substitution. Each of these PCB congeners has a unique profile of fates and effects in the environment. The biological effects of PCBs are highly congener-specific and can be expressed primarily through the AhR pathway (Okey et al., 1994). As a result, PCB toxicity, like PCDD and PCDF toxicity, can be assessed by converting congener-specific data to TEQs using appropriate TEF or RPF values (Table 3-2, Van den Berg et al., 1998). The toxic effects of PCBs include biochemical adaptive changes such as enzyme induction, developmental deformities, reproductive failure, hormonal changes, liver damage, wasting syndrome, and death (Gilbertson et al., 1991; Heaton et al., 1995; Brunstrom et al., 2001; Restum

et al., 1998). Since the primary mechanism of action for PCBs involves activation of the AhR pathway, similarly to PCDDs and PCDFs, congener-specific analysis of PCBs will be conducted on a portion of the samples to gain an understanding of the relative contribution of PCBs to the total TEQ concentrations.

Table 3-2. Mammal, fish, and bird-specific toxic equivalency factors (TEFs) from the World Health Organization (WHO) for the non-*ortho* and mono-*ortho* substituted PCBs.

		WHO 1998 TEF Values		
		Mammals/ Humans	Fish	Birds
non-*ortho* PCBs				
	3,3',4,4'-TCB (77)	0.0001	0.0001	0.05
	3,4,4',5-TCB (81)	0.0001	0.0005	0.1
	3,3',4,4',5-PeCB (126)	0.1	0.005	0.1
	3,3',4,4',5,5'-HxCB (169)	0.01	0.00005	0.001
mono-*ortho* PCBs				
	2,3,3'4,4'-PeCB (105)	0.0001	< 0.000005	0.0001
	2,3,4,4',5-PeCB (114)	0.0005	< 0.000005	0.0001
	2,3',4,4',5-PeCB (118)	0.0001	< 0.000005	0.00001
	2',3,4,4',5-PeCB (123)	0.0001	< 0.000005	0.00001
	2,3,3',4,4',5-HxCB (156)	0.0005	< 0.000005	0.0001
	2,3,3',4,4',5'-HxCB (157)	0.0005	< 0.000005	0.0001
	2,3',4,4',5'-HxCB (167)	0.00001	< 0.000005	0.00001
	2,3,3',4,4',5,5'-HpCB (189)	0.0001	< 0.000005	0.00001

Source: Van den Berg et al., 1998

3.2.3 Organochlorine Pesticides

DDT (dichlorodiphenyltrichloroethane) is an organochlorine insecticide that was used in the United States prior to 1972 and is still used in parts of Africa, Asia, and Central and South America mainly to control mosquito-borne malaria. DDT is highly persistent in the environment, with a reported half-life of between 2-15 years (Augustijn-Beckers et al., 1994). DDT and its metabolites have been shown to cause eggshell thinning and consequent adverse effects on development and reproduction in various bird populations (Blus et al., 1997; Lundholm, 1997; King et al., 2003).

From approximately 1936 until the early 1970s, Michigan Chemical/Velsicol Corporation produced various brominated and chlorinated chemicals, which were released into Pine River, an upstream tributary of the Tittabawassee River. DDT was released into the Pine River environment due to activities at the Velsicol Chemical Company and consequently became a primary contaminant of concern in this area. Elevated concentrations of DDT and its metabolites, have been measured in Pine River sediments and various fish species resulting in fish consumption advisories (MDEQ 2000). Because of the continued presence of DDT and its metabolites within this system and possible additional inputs via atmospheric deposition, organochlorine pesticides, especially DDT and its metabolites, may pose risks toward avian wildlife in the Tittabawassee River study area. Therefore, DDT and its metabolites are COPECs that will be evaluated in this investigation.

3.3 Identification of Potential Ecological Receptors

It is not feasible to evaluate exposures and risks for each avian and mammalian species potentially present within the study area. For this reason, specific, representative wildlife species are identified as receptors of concern (ROCs) for the purpose of estimation of quantitative exposures (doses) in the BERA. USEPA ERA guidance recommends selecting receptors that have a great likelihood of exposure and sensitivity to COPECs, ideally with home ranges that are of similar magnitude to the size of the site. The selection of receptors for consideration in this BERA Work Plan was based on compliance with USEPA ERA guidance (as stated above) and consideration of other factors such as life history parameters, presence or likely presence at the site, representativeness of receptor class (e.g., mink as a representative species for piscivorous mammals), and availability of toxicological data for these and similar species. Threatened and endangered species that have potential to be present on the site will be evaluated in consultation with USFW.

3.3.1 Species Selected as Receptors of Concern or Assessment Endpoint Species

Receptors that are the focus of this BERA Work Plan are summarized in Table 3-3. Both aquatic and terrestrial ecological receptors have been selected. However, it is important to note that some of these receptors are opportunistic predators that can occasionally have site-specific diets that include a mixture of aquatic and terrestrial pathways. For example, great horned owls typically eat terrestrial-based diets but have been known to consume muskrats and great blue herons which are linked to aquatic based exposures. Thus, site-specific dietary composition will be characterized for each of the selected ecological receptors when possible. All of the specific target species have been confirmed to be present at the site.

By collecting a diverse array of food web items in both the terrestrial and aquatic habitats, the BERA Work Plan is flexible and can readily accommodate other ROCs as they are identified. Furthermore, this workplan allows for the use of data from studies with receptors not currently identified in this workplan (Table 3-3) including migratory waterfowl.

Table 3-3. Proposed receptors for the ERA Work Plan

Receptor Group	Food Web	Representative Species
Small herbivorous mammals	Terrestrial	Meadow vole (*Microtus pennsylvanicus*)
Small insectivorous/ carnivorous mammals	Terrestrial	Short-tailed shrew (*Blarina brevicauda*)
Insectivorous passerine	Terrestrial	House wren (*Troglodytes aedon*)
Vermivorous /insectivorous passerine	Terrestrial	American robin (*Turdus migratorius*)
Carnivorous birds	Terrestrial	Great horned owl (*Bubo virginianus*)
Piscivorous mammals	Aquatic	Mink (*Mustela vison*)
Insectivorous passerine	Aquatic	Tree swallow (*Tachycineta bicolor*)
Piscivorous birds	Aquatic	Belted kingfisher (*Ceryle alcyon*)
	Aquatic	Great blue heron (*Ardea herodias)*

3.3.2 Species Not Selected as Receptors of Concern or Assessment Endpoint Species

Other receptors that were considered but were not included as ROCs in this BERA Work Plan include benthic invertebrates, terrestrial invertebrates, reptiles, and amphibians, for the reasons discussed below.

3.3.2.1 Terrestrial and Aquatic Invertebrates

Terrestrial and aquatic invertebrates are critical dietary components of food webs. In addition, since they are in direct contact with and ingest relatively great quantities of soils and sediments, respectively, they affect the bioavailability of particulate-bound COPECs to higher level receptors. Therefore, terrestrial and aquatic invertebrates will be collected in order to estimate COPEC exposures to organisms that feed on them. However, since such invertebrate organisms lack a functional AhR-mediated pathway, they are not expected to be directly affected by COPECs, such as PCDDs and PCDFs. Thus, the main reason for exclusion of terrestrial and aquatic invertebrates as ROCs is their lack of sensitivity to PCDDs and PCDFs.

3.3.2.2 Reptiles and Amphibians

Reptiles and amphibians, while present at the site, were not selected as receptors of concern because of a lack of toxicity data. Although basic ecological information is available for a large number of reptiles, "it is often the lack of sufficient toxicity data in the literature that precludes the use of reptiles as receptors in ecological risk assessments" (Sparling et al., 2000, p. 799). Literature-based information for reptiles and COPECs is limited to tissue residue data with no emphasis on actual effects on individuals or populations. Although toxicity benchmark or threshold values are available for a number of organisms, such values do not exist for reptiles, although research efforts are currently focusing on this data gap. For amphibians, there is toxicological data to indicate that they are not particularly sensitive to AhR-mediated effects (Beatty et al., 1976; Korfmacher et al., 1986). The general observation that amphibians may not be very sensitive to AhR-mediated effects is further supported by the fact that the affinity of TCDD to the AhR in *Xenopus laevis* is low when compared to other species (Elskus 2005; Lavine et al. 2005). Nevertheless, amphibians will be collected and analyzed for COPECs as a dietary item for other wildlife.

3.4 Selection of Assessment Endpoints

Assessment endpoints are explicit expressions of the environmental values that are to be protected. Assessment endpoints are general, large-scale expressions of environmental components or characteristics that may be at risk, and therefore, require protection. The assessment endpoints selected in this ERA are based on the protection of the reproductive success and population sustainability of the selected receptor species of concern (Table 3-4). For several species, measures of reproductive success are sensitive response endpoints indicating contaminant toxicity (Tillitt et al., 1996; Foster, 1995). In addition, reproductive success endpoints are influential indicators of population sustainability.

Table 3-4. Proposed receptor species and associated assessment endpoints for the BERA.

Receptor Species	Assessment Endpoint
Small mammals - Meadow vole, short-tailed shrew	Reproductive success and population sustainability
Mink	Reproductive success and population sustainability
Raptors - Great horned owl	Reproductive success and population sustainability
Passerine birds – Tree swallow, house wren, American robin	Reproductive success and population sustainability
Piscivorous birds – Belted kingfisher, great blue heron	Reproductive success and population sustainability

3.5 Identification of Potential Exposure Pathways and Development of a Conceptual Site Model

The previously described parameters, including fate and transport characteristics of COPECs, have been combined into a conceptual model that represents potential exposure pathways of COPECs from potential sources to relevant biological receptors (Figure 3-1 and Figure 3-2). These pathways include a number of ingestion and direct contact pathways.

The primary exposure pathways for aquatic food chain receptors identified in this evaluation include:

- Direct exposure to COPECs in surface water and sediment via primary producers (e.g., aquatic plants), and
- Direct exposure to COPECs in surface water, sediment, and dietary items by primary, secondary, and tertiary consumers (e.g., aquatic and benthic invertebrates, muskrats, fish, and avian and mammalian wildlife).

The primary exposure pathways for terrestrial food chain receptors identified in this evaluation include:

- Direct exposure to COPECs in floodplain soils via primary producers (e.g., plants), and
- Direct exposure to COPECs in surface water, soil, terrestrial plants, and other dietary items by primary, secondary, and tertiary consumers (e.g., earthworms and other terrestrial invertebrates, and avian and mammalian wildlife).

3.6 Risk Questions

Ecological risk questions establish the relationship between assessment endpoints and their expected responses when exposed to contaminants. Measurement endpoints are then used to answer risk questions for each COPEC and ROC exposure pathway. Measurement endpoints are related qualitatively or quantitatively to the assessment endpoints (USEPA 1997). There are three categories of measurement endpoints: (1) Measures of adverse effects, which include adverse changes in the population health of ROCs or their surrogates in response to a COPEC or other stressor; (2) Measures of exposure, which include a determination of exposure of a ROC to a COPEC or other stressor; and (3) Measures of

ecosystem and ROC characteristics, which include measure of characteristics that influence the behavior and location of entities within the system under study. In the case of this BERA, the risk question is:

- Does exposure to site-related COPECs result in unacceptable risks to receptors of concern based on measures of reproductive success and population sustainability?

As data related to measures of effect, exposure, and ecosystem and receptor characteristics will be collected during the conduct of this BERA, multiple lines of evidence will be used to answer questions of risk. Evaluation of multiple lines-of-evidence has been defined as "*the process by which multiple measurement endpoints are related to an assessment endpoint to evaluate whether [unacceptable risk] is posed to the environment*" (Massachusetts Weight-of-Evidence Workgroup, 1995). Various approaches have been proposed to take into account multiple lines of evidence in wildlife risk assessments (Menzie et al. 1996, Fairbrother, 2003). In general these are tiered approaches that evaluate information from dietary exposures (predicted or measured), dose-response relationships, and field studies of population and/or community responses (USEPA 1997, 1998). Each line of evidence that is examined in this type of analysis has different predictive capabilities due to the fact that each is based on different assumptions that include differing degrees of uncertainty. As a result, no single line of evidence is sufficient to accurately estimate the magnitude and extent of the risk that a stressor or group of stressors may pose to a receptor.

A lines-of-evidence approach may either be quantitative or qualitative. The first step in the multiple-lines-of-evidence approach is to evaluate measurement endpoints for each of the following three attributes:

1. Strength of association between assessment and measurement endpoints;

   This attribute examines the biological linkage between a measurement endpoint and its associated assessment endpoint based on the similarity of effect, target organ, mechanism of action and level of ecological organization. In addition, the ability of an endpoint to demonstrate effect from an exposure as well as to correlate with the degree of exposure is also examined. Finally, the applicability, uncertainty, scientific basis and sensitivity of the measurement endpoint are examined.

2. Data quality;

   This attribute examines the extent to which data quality objectives have been met relative to the appropriateness of the data collection and analysis practices.

3. Study design and execution;

   This attribute examines the extent to which a measurement endpoint reflects potential changes in assessment endpoints due to stressors present within the study site. Factors that are taken into consideration include: (a) site-specificity of chemical and biological data and benchmarks used to evaluate effects at the site; (b) sensitivity of the measurement endpoint to detect changes; (c) spatial and temporal representativeness of measurement endpoints to changes in assessment endpoints at the site; (d) quantitativeness of the measurement to allow for statistical evaluations; and (e) use of standard method/protocols such that the data collected at the site are suitable and applicable to addressing potential risk questions.

The second step in the multiple lines-of-evidence approach is to evaluate the outcome of each measurement endpoint with respect to the potential for unacceptable risk (e.g., positive, negative, and undetermined). In this part of the analysis, changes in each measurement endpoint will be evaluated relative to its ecological relevance as to the extent of spatial and temporal changes within the site as

compared to reference conditions. In addition, the magnitude of the outcome (e.g., high or low) for each measurement will be evaluated as well as the presence of any gradients in the response within the study site.

The third step in the multiple lines-of-evidence approach is to integrate the relative strength of each measurement endpoint (e.g., based on the three attributes described above) and the magnitude of response on a matrix in order to determine whether the overall evidence indicates the presence of unacceptable risk. Each measurement endpoint will be evaluated relative to how it relates to each specific assessment endpoint.

In ecological risk assessment, two general approaches can be used to evaluate the risk that chemicals may pose to ROCs (Fairbrother 2003; Suter 2004). The tissue-based approaches and population measures take a macro scale view of existing on-site conditions by comparing them to literature-based TRVs and off-site reference conditions as a means to evaluate the potential effect of contaminants at the site. In these approaches, analyses are typically based on tissue residue concentrations and population information collected from field studies. In the dietary-based approach, measured concentrations in environmental media (e.g. water, soil, sediment) and dietary items are used in food web models to estimate exposure of ROCs to contaminants identified at the site and reference locations. This approach, unlike the tissue-based approach provides a more detailed evaluation of the exposure pathways of contaminants at the site to ROCs but can include a greater amount of uncertainty due to the many assumptions used to estimate exposure. Overall, both approaches provide valuable insights into the exposure of ROCs to contaminants at the site as well as information on the relative importance of specific exposure pathways to these receptors. As a result, the lines-of-evidence approach will be applied to all data collected at the site for ROCs. In those instances where only a single line of evidence is available, the first step in the multiple-lines of evidence will be utilized and the result summarized in the assessment of uncertainties that are associated with this risk evaluation. In instances where multiple measurement endpoints are utilized for a single assessment endpoint all three steps in the multiple-lines-of-evidence approach will be utilized. In this situation, risk calculations based on dietary exposure estimates and tissue residue concentration in receptors of concern, along with productivity data for receptor species of concern will constitute a multiple lines-of-evidence evaluation for ecological risk questions posed for the Site (Millsap et. al., 2004). Many of the MSU Aquatic Toxicology Laboratory study plans for the Site are multi-year studies that include collection of data relevant to multiple lines of evidence for individual receptors. The timeframe for the BERA is intended to provide the most pertinent information to decision makers. Information that is available from the studies within the BERA reporting timeframe will be included in the risk assessment analysis. It is anticipated that all relevant data will be available for the dietary based exposure assessment; while only certain tissue data will be available for ROCs to support a tissue residue-based analysis, and certain measures of reproductive success will be available for a very limited selection of receptors (Table 1-1). The relationship among assessment and measurement endpoints, which comprise the lines of evidence, is provided in Table 3-5.

Table 3-5. Relationships between assessment and measurement endpoints.

Assessment Endpoint	Measurement Endpoints
1. Reproductive success and population sustainability of small mammals (e.g., meadow vole, short-tailed shrew).	A. Comparison of estimated dietary exposure concentrations of COPECs to dietary toxicity reference values (TRVs) that are designed to be protective of small mammals. B. Comparison of site-specific, field measured tissue residue concentrations of COPECs in small mammals to tissue residue-based TRVs from literature-derived studies
2. Reproductive success and population sustainability of mink.	A. Comparison of estimated dietary exposure concentrations of COPECs to dietary toxicity reference values (TRVs) that are designed to be protective of mink. B. Comparison of site-specific, field measured tissue residue concentrations of COPECs in mink to tissue residue-based TRVs from literature-derived studies C. Comparison of site-specific, field-measured population measures between site and reference locations.
3. Reproductive success and population sustainability of great horned owls.	A. Comparison of estimated dietary exposure concentrations of COPECs to dietary toxicity reference values (TRVs) that are designed to be protective of great horned owls. B. Comparison of site-specific, field measured tissue residue concentrations of COPECs in great horned owls to tissue residue-based TRVs from literature-derived studies C. Comparison of site-specific, field-measured population measures between site and reference locations.
4. Reproductive success and population sustainability of house wrens.	A. Comparison of estimated dietary exposure concentrations of COPECs to dietary toxicity reference values (TRVs) that are designed to be protective of house wrens. B. Comparison of site-specific, field measured tissue residue concentrations of COPECs in house wrens to tissue residue-based TRVs from literature-derived studies C. Comparison of site-specific, field-measured population measures between site and reference locations.

5. Reproductive success and population sustainability of American robins.	A. Comparison of estimated dietary exposure concentrations of COPECs to dietary toxicity reference values (TRVs) that are designed to be protective of American robins. B. Comparison of site-specific, field measured tissue residue concentrations of COPECs in American robins to tissue residue-based TRVs from literature-derived studies
6. Reproductive success and population sustainability of tree swallows.	A. Comparison of estimated dietary exposure concentrations of COPECs to dietary toxicity reference values (TRVs) that are designed to be protective of tree swallows. B. Comparison of site-specific, field measured tissue residue concentrations of COPECs in tree swallows to tissue residue-based TRVs from literature-derived studies C. Comparison of site-specific, field-measured population measures between site and reference locations.
7. Reproductive success and population sustainability of belted kingfishers.	A. Comparison of estimated dietary exposure concentrations of COPECs to dietary toxicity reference values (TRVs) that are designed to be protective of belted kingfishers. B. Comparison of site-specific, field measured tissue residue concentrations of COPECs in belted kingfishers to tissue residue-based TRVs from literature-derived studies C. Comparison of site-specific, field-measured population measures between site and reference locations.
8. Reproductive success and population sustainability of great blue herons.	A. Comparison of estimated dietary exposure concentrations of COPECs to dietary toxicity reference values (TRVs) that are designed to be protective of great blue herons. B. Comparison of site-specific, field measured tissue residue concentrations of COPECs in great blue herons to tissue residue-based TRVs from literature-derived studies C. Comparison of site-specific, field-measured population measures between site and reference locations.

3.7 Scientific Management Decision Point #2

As part of the problem formulation phase of the BERA several decision points will be reached. These decisions will be made in consultation with the MDEQ and other appropriate stakeholders and pertain to:

- The refined selection of COPECs for the BERA;
- The selection of assessment endpoints to be evaluated in the BERA;
- The formulation of the relevant contaminant exposure pathways at the site under investigation; and
- The overall risk question to be evaluated in the BERA.

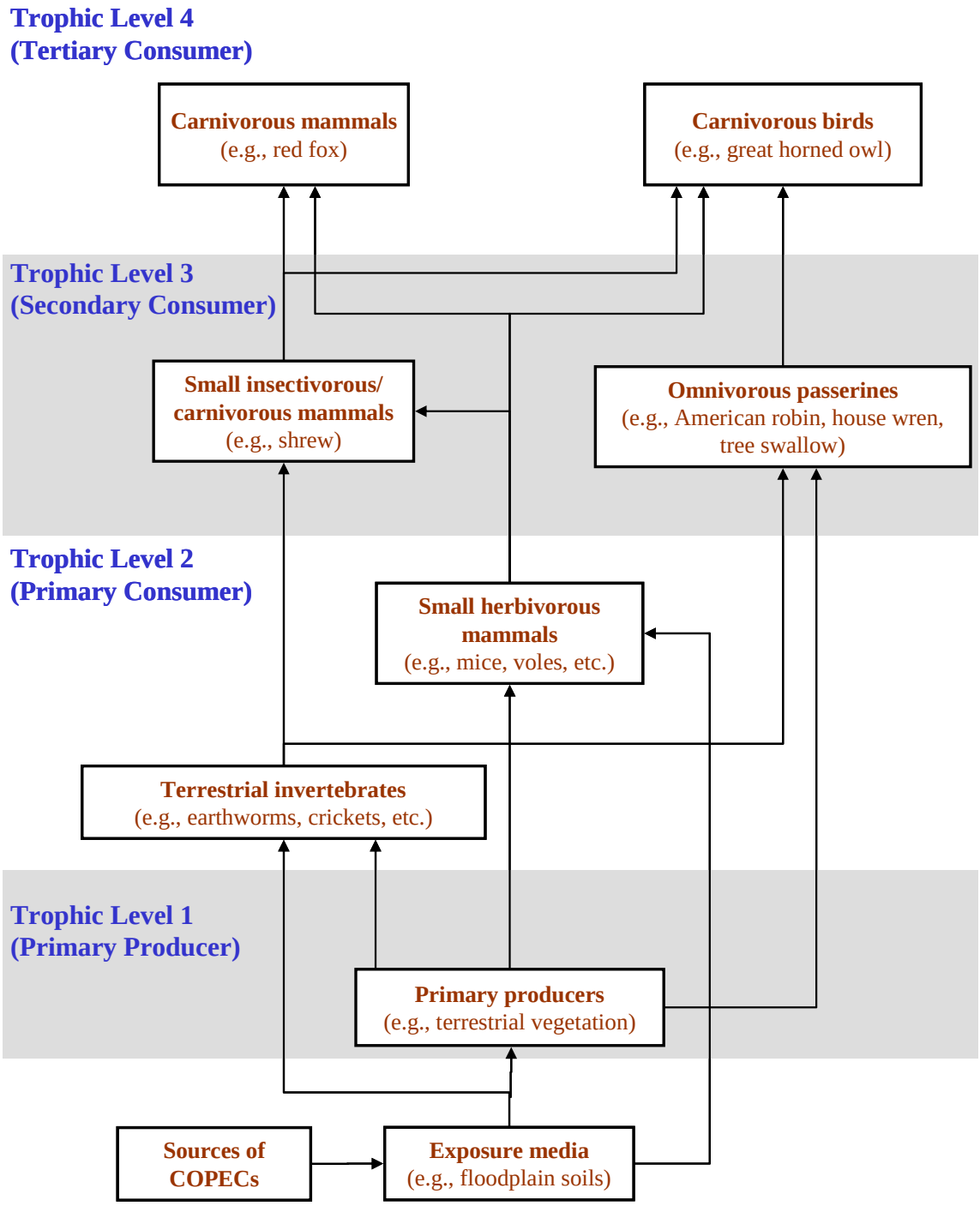

Figure 3-1. Conceptual model schematic of potential terrestrial exposure pathways.

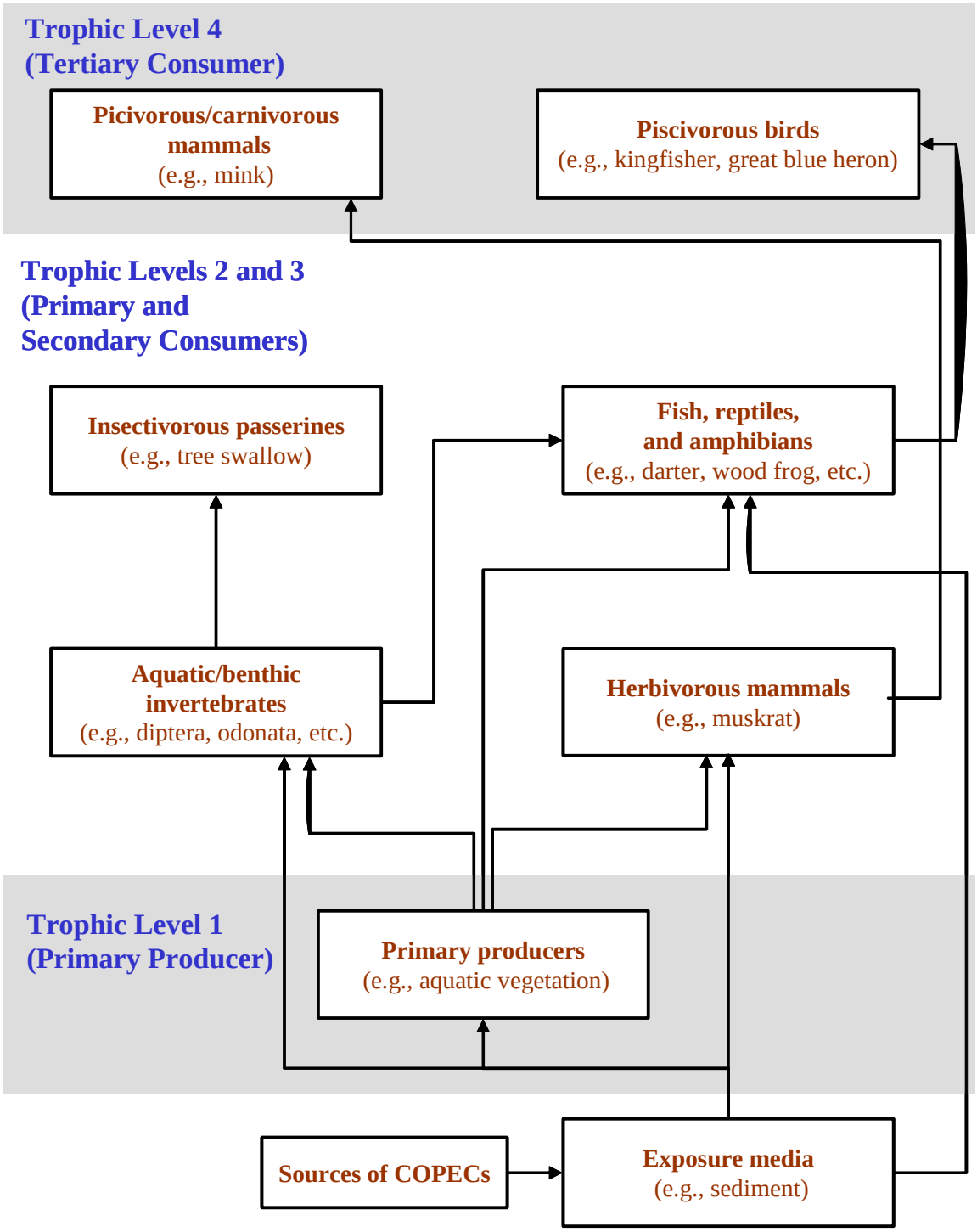

Figure 3-2. Conceptual model schematic of potential aquatic exposure pathways.

4.0 BASELINE ERA STUDY DESIGN PHASE

4.1 Introduction

During the study design phase, data quality objectives are developed for the BERA, measurement endpoints are selected, and sampling and analysis plans are developed based on decisions made in the problem formulation phase of the assessment. The exposure pathway and receptor-specific investigations in this study are presented in appendices D-G as separate study plans.

4.2 Data Quality Objective Process

The DQO process is a planning tool involving a series of steps designed to ensure that the type, quantity, and quality of environmental data used for decision-making purposes are appropriate for the intended application (USEPA 2000a and 2000b). The DQO process, as defined by USEPA, is "...a strategic planning approach based on the Scientific Method that is used to prepare for a data collection activity. It provides a systematic procedure for defining the criteria that a data collection design should satisfy, including when to collect samples, where to collect samples, the tolerable level of decision errors for study, and how many samples to collect." The steps in the DQO process, as established by USEPA, are as follows:

1. Formulation of Problem Statements. This step concisely describes the problems to be studied.
2. Identification of Decisions. This step consists of accurately describing the questions to be answered that will solve the specified problems, including any actions that may result.
3. Identification of Inputs to Decisions. This step focuses on identifying qualitative and quantitative information that will support decision-making, including the types of measurements that will be required.
4. Definition of Study Boundaries. This step delineates the spatial and temporal boundaries that will be encompassed by the study and describes when and where data shall be obtained. This includes specifying characteristics of the (statistical) population of interest, defining the geographical extent of the area and timeframes to which decisions will apply, and identifying constraints on obtaining data.
5. Development of Decision Rules. This step defines the statistical measures relevant to the study and specifies the conditions by which decision-makers will choose among alternative actions.
6. Specification of Decision Error Limits. This step specifies tolerable false positive and false negative decision errors and develops statements concerning the consequences of making incorrect decisions.
7. Optimization of Sampling Design. This step considers information obtained in the previous six steps to formulate an optimal sampling design, including (if possible) estimates of the number of samples necessary to meet acceptable decision errors.

Barnthouse and Suter (1996) point out the difficulties in applying the last three steps in the DQO process to ERAs since:

1. there are no officially approved standards or environmental goals for ecological endpoints,
2. an assessment may have multiple endpoints, and

3. ecological risk assessments often involve weight-of evidence evaluations of qualitatively different types of measurements (e.g., contaminant concentrations, population or community measurements, biomarkers, toxicity tests).

Barnthouse and Suter (1996) also state that because of the complexity of the data, the decision alternatives cannot be formulated as probabilistic hypotheses with confidence limits; therefore, simple optimization rules cannot be followed. Given these constraints, the DQOs are discussed in the appendices to this BERA Work Plan to the extent that is possible at this stage of the process. Each of the steps in the DQO process, including problem statement, decision identification, decision inputs, spatial and temporal boundaries, decision rules, limits for decision errors, and optimized sampling design, produce qualitative and quantitative statements that are used to develop a scientifically sound and resource-effective sampling design.

A detailed DQO section, including the seven steps in the process, is presented within each individual study plan (Appendices C-G).

4.3 Sample Collection Methods

Receptor-specific sampling and analysis plans in Appendices C through G provide individual study details for preparation, monitoring, and collection methods for the various target species. Study Plan I - Exposure Pathway Analysis (Appendix C) describes the rationale and sampling methods for lower food web organisms that will be collected from reference areas and from the Site such that dietary exposure can be estimated for receptor species of concern. Study Plan II – Evaluation of Mink - Abundance, Health, Stressor Exposure, and Habitat Suitability (Appendix D) presents the rationale and methods for mink population investigations at the Site. Study Plan III – Evaluation of Passerines – Stressor Exposure, Reproductive Success, and Habitat Suitability (Appendix E) presents the rationale and methods for passerine population investigations at the Site. Study Plan IV – Evaluation of Raptors – Stressor Exposure and Reproductive Success (Appendix F) presents the rationale and methods for bald eagle and great horned owl population investigations at the Site. Finally, Study Plan V – Evaluation of Piscivorous Birds – Stressor Exposure, Reproductive Success, and Habitat Suitability (Appendix G) presents the rationale and methods for belted kingfisher and great blue heron population investigations at the Site.

4.4 Analytical Methods

4.4.1 Selection of Analytical Suite

Based on available historical data, the primary COPECs at the Site are the 17 PCDD and PCDF congeners that have chlorine substitution at the 2,3,7,8 positions. Thus, analyses of all biotic and abiotic samples will include this suite of 17 PCDD and PCDF congeners. In addition, a subset of avian tissue samples will be analyzed for DDT and its metabolites. Other COPECs, including PCBs, may be analyzed in samples based on findings from the SLERA.

4.4.2 Analytical Methodology and Detection Limits

Samples collected during this Work Plan will be processed and homogenized at the ATL. Analyses will be conducted at the ATL and also at AgriQuality Limited, 1B Bell Road, PO Box 31-242, Lower Hutt, New Zealand. The Limits of Detection (LODs) are based on currently acceptable laboratory performance for certified EPA standard methods 1613 and 8290. The analysis of PCDD and PCDF congeners is particularly susceptible to matrix-based interferences that can significantly alter sample-specific detection limits. Therefore, the data quality objectives provided in Table 4-1 must be considered as ‘targets’ and not absolute criteria. All efforts shall be made by the laboratory to attain these detection limits. In addition, exceedance of any of these targets for a laboratory (reagent) blank sample could require

reanalysis of that batch of samples. Standard reference materials will be included in the samples analyzed. However, when standard reference materials do not exist for these specific tissue types, the most suitable available substitutes will be used. In addition, matrix spike samples based on the collected tissues will also be analyzed.

Table 4-1. Target detection limits for PCDDs and PCDFs

Chemical	LOD (pg/g)	Chemical	LOD (pg/g)
2378-TCDD	0.1	PCB#77	0.05
2378-TCDF	0.1	PCB#81	0.05
12378-PeCDD	0.3	PCB#126	0.005
12378-PeCDF	0.3	PCB#169	0.02
23478-PeCDF	0.3	PCB#105	0.05
123478-HxCDD	0.5	PCB#114	0.05
123678-HxCDD	0.5	PCB#118	0.05
123789-HxCDD	0.5	PCB#123	0.05
123478-HxCDF	0.5	PCB#156	0.05
123678-HxCDF	0.5	PCB#157	0.05
234678-HxCDF	0.5	PCB#167	0.5
123789-HxCDF	0.5	PCB#189	0.05
1234678-HpCDD	0.5		
1234678-HpCDF	0.5		
1234789-HpCDF	0.5		
OCDD	1		
OCDF	1		
TOTAL WHO-TEQ	0.9	TOTAL WHO-TEQ	0.8

LOD = Limit of detection.

4.5 Data Analysis and Interpretation

As part of the BERA, sample information, analytical results, and results of statistical comparisons will be reported.

4.5.1 Sample Information

Sample-specific information will be reported for each specimen or sample composite collected during BERA investigations (Table 4-2). Reported information will include both field and laboratory data, such as matrix or tissue type, location and time of sample collection, environmental conditions during field collections, sex and age (if applicable) of the collected specimen, as well as percent lipid content and COPEC concentration in the analyzed sample.

Table 4-2. Field and laboratory information for ERA samples

Sample Information	Specifically Reported Parameter
Sample Descriptions	• Laboratory and field ID • Species and scientific name • Classification of specimen (order reported for insects) • Matrix and tissue type • Sex (if applicable and determinable) of specimen collected • Age of specimen (if determinable)
Location of Field Collection	• Reach location • Grid location • GPS coordinates (Northing and Westing)
Date and Time of Field Collection	• Round of collection • Date of collection • Time of collection
Other Conditions of Field Collections	• Temperature and weather conditions when collected • Method of field collection
Analytical information	• Percent lipids (for biota) • Percent moisture (if applicable) • Percent organic carbon (for soils and sediments) • PCDD and PCDF congener specific concentration • Wet weight and lipid normalized TEQ concentrations (based on either mammalian, avian, or fish TEFs)

4.5.2 Analytical Data Packages

In addition to the reported sample information, laboratory data will be reported in an analytical data package. This package will, at a minimum, include a narrative that will discuss any problems or discrepancies, and sufficient calibration and QC information to determine that the method was in control at the time that the samples were analyzed. The laboratory records included in an analytical data package will include:

- Case narrative;
- COC documentation (external);
- Laboratory sample ID, field sample ID, location, matrix, and dilution factors;
- Sample receipt, extraction, and analysis dates for holding time verification;
- Percent recovery of each surrogate;
- Final analyte concentration including reporting limit, laboratory qualifiers, and re-analyses;
- Surrogate recovery control limits;
- Percent recovery of each compound in the MS sample;

- Matrix spike (MS) recovery control limits;
- Relative percent difference (RPD) for all MS/MS Duplicate (MSD) and/or laboratory control sample (LCS)/LCS Duplicate (LCSD) reports;
- RPD control limits for MS/MSD and/or LCS/LCSD reports;
- Laboratory control sample results when analyzed;
- Recovery control limits for LCS or Standard reference material (SRM) recoveries and RSD;
- Blank results for method blanks, field blanks, equipment blanks, and trip blanks; and
- Method blank summary indicating associated samples.

In addition to the hard-copy report requirements, the laboratory will provide (1) electronic deliverables conforming to an ASCII comma-delimited format for all data reported and (2) an electronic back up for all laboratory data generated.

4.5.3 Descriptive Statistics

Descriptive statistics of the results will be reported for all samples collected from the reference and downstream locations. Descriptive statistics will include at a minimum, the sample size, arithmetic mean, the upper 95 percent confidence interval of the mean, standard deviation of the mean, and minimum and maximum values. When calculating descriptive statistics, one-half of the method detection limit (MDL) will be substituted for non-detect concentrations. One-half the MDL will be used only for those compounds and congeners otherwise detected in the relevant area. Descriptive statistics will be provided for concentrations of individual PCDD, PCDF, other potential COPECs, and total TEQs (on a wet weight and lipid normalized basis) and will be stratified by site, species (or matrix), and tissue (if applicable).

4.5.4 Comparative Statistics

Comparative statistical tests will be conducted and results of these analyses will be reported as part of the BERA investigation. Table 4-3 summarizes the statistical comparisons that will be conducted in the BERA.

Before hypothesis tests are conducted, data sets will be evaluated to determine if parametric or non-parametric statistics will be used in the analyses. Parametric statistics assume that the data distribution is normal or bell-shaped and the variances of each population are homogeneous (equal). Non-parametric statistical tests are not dependent on a specific distribution; rather, they are “distribution-free” and can be used to test the distribution of data relative to different types of distribution functions. The data from each site will first be tested for a normal distribution by using the One Sample Kolmogorov-Smirnov test with Lillifor’s transformation (Table 4-3; Wilkinson, 2000). If data for a species and or tissue type at a location are not normally distributed, then the data will be log-transformed and the data set re-tested. To determine if the variances are homogeneous in the data sets, one of two tests will be used depending on the number of locations being evaluated. For two locations, the variances of samples collected from each of the reference and downstream locations will be tested by an F-Test. If greater than 2 locations are to be evaluated, a Levene’s Test will be conducted to evaluate variance homogeneity (Table 4-3; Wilkinson, 2000). If the data are not normally distributed or do not have homogeneous variances, then the use of parametric statistics becomes suspect and the results difficult to interpret. Under this scenario, a non-parametric statistical test would be used.

If data meet the requirements for parametric tests, then a Student’s t-test (equal sample sizes) or the tabled t-test (unequal sample sizes) will be used to compare TEQ concentrations between two locations. If more

than two locations are compared, an ANOVA with Tukey's Honestly Significant Difference (HSD) will be used to compare TEQs among locations (Table 4-3; Wilkinson, 2000).

If data are not normally distributed and/or do not meet the criteria for homogeneous variances, then non-parametric statistical tests will be used to evaluate differences between or among locations. If only two locations are to be tested, a Mann-Whitney U test will be used to evaluate differences between locations. If greater than 2 locations are to be evaluated, then the Kruskal-Wallis test will be used for statistical analyses (Table 4-3; Wilkinson, 2000).

Table 4-3. Statistical evaluations and statistical tests that will be used in the BERA investigation

Statistical Evaluations	Statistical Test
Normalcy	One sample Kolmogorov-Smirnov with Lillifor's transformation
Variance homogeneity	F-test or Levene's test
Comparison between two data sets (parametric assumptions met)	Student's t-test or tabled t-test
Comparison between two data sets (parametric assumptions not met)	Mann-Whitney U
Comparison among three or more data sets (parametric assumptions met)	ANOVA with Tukey's HSD
Comparison among three or more data sets (parametric assumptions not met)	Kruskal-Wallis
Congener pattern analysis	Principal components analysis (PCA)

4.6 Scientific Management Decision Point #3

At the close of the study design phase of the BERA, several decision points will have been reached that will address the endpoints and methodologies for data collection and interpretation. These decisions wil be made in consultation with the MDEQ and other appropriate stakeholders and pertain to:

- Measurement endpoints;
- Investigative methods; and
- Data interpretation and analysis techniques.

5.0 BASELINE ERA ANALYSIS PHASE – EXPOSURE AND EFFECTS ASSESSMENT

During the analysis phase, exposure to stressors and the relationship between stressor concentrations and ecological effects are evaluated.

5.1 Exposure Assessment

The purpose of the exposure assessment phase is to evaluate exposure of receptors to chemical stressors. This phase involves collection and integration of information on COPECs, COPEC concentrations and spatial distribution, and exposure conditions (temporal and spatial patterns). Exposure point concentrations of COPECs will be determined and compared to toxicity reference values (TRVs) in order to calculate the potential for adverse effects. As outlined in Section 3.6, the two primary approaches for assessing exposure and effects of persistent, bioaccumulative COPECs in wildlife assessments are the dietary-based and receptor tissue-based approaches (Fairbrother, 2003; Millsap et. al., 2004). Each of these approaches will be discussed in the following sections.

5.1.1 Dietary Exposure Modeling Approach

The dietary-based method is one of the most widely used approaches to assess wildlife exposure, ranging from simplistic to complex. In general, an average daily dose is calculated by food web modeling in which one makes assumptions regarding dietary composition, applies bioaccumulation models (if necessary), and utilizes concentrations of residues measured at lower levels of the food chain, soil, and sediment. In a screening level ERA, this can be based on very limited data. However, as one moves into a BERA, this approach accommodates more site-specific data including dietary composition data for individual receptors and concentrations of residues in dietary items. The exposure that is calculated from this dietary-based approach can then be compared to dietary-based toxicity reference values (TRVs) derived from dietary exposures (Refer to section 5.2.1.1 for a discussion of dietary-based TRVs).

5.1.1.1 Exposure Characteristics of Avian and Mammalian Wildlife Receptors

Characteristics of key receptors will be clearly presented in the BERA, including exposure assumptions for body weight, ingestion rate, dietary composition, area use factor, etc. The primary source of exposure assumptions is the USEPA Exposure Factors Handbook (USEPA, 1993). Additional sources of information include primary peer-reviewed scientific literature, site surveys, and professional judgment, and other compendia of region-specific and species-specific information (Sample and Suter, 1994). Whenever available, site-specific and/or region-specific exposure information will be utilized. The selected species might be exposed to COPECs through contact with and/or ingestion of contaminated media (e.g., primarily through dietary exposure). Exposure estimates for all species will be calculated for COPECs detected in dietary items and incidental soil ingestion.

Exposure calculations will be conducted with exposure concentrations derived from either measured concentrations of COPECs or concentrations predicted from models in the relatively rare case when no measured concentrations are available. Bioaccumulation models are often fraught with uncertainty because bioavailability depends upon highly variable site-specific considerations such as soil type, pH, moisture, clay content, organic carbon, cation exchange capacity, exposure duration, and receptor-specific considerations such as uptake mechanisms. In particular, available information suggests that bioavailability from soil to biota is limited for many COPECs. Thus, to minimize uncertainty, concentrations of COPECs will be measured in the dietary exposure pathways of herbivorous and carnivorous wildlife utilizing the site. Exposure to COPECs from water ingestion, inhalation and dermal

contact were considered negligible for the purposes of this BERA based on the fate and transport characteristics of site-related COPECs (USEPA 2003b). Direct ingestion of soil or sediment was considered for certain wildlife since wildlife may experience substantial contaminant exposure through direct ingestion of soil or sediment.

5.1.1.2 Estimation of Oral Exposure for Avian and Mammalian Wildlife Receptors

Estimates of daily contaminant exposure experienced by individual receptor species are calculated using a modification of the generalized exposure model presented by USEPA (2003b). The generalized exposure model is depicted (Eq. 5-1):

Eq. 5-1

$$ADD_{pot} = \frac{\left[\left(C_{soil} \text{ x } IR_{soil} \text{ x } AF_{soil}\right) + \left(C_{sed} \text{ x } IR_{sed} \text{ x } AF_{sed}\right) + \left(\sum_{i=1}^{N} C_{diet(i)} \text{ x } \left(P_i \text{ x } FIR\right)\right)\right] \text{ x } AUF}{BW}$$

Where:

ADD_{pot} = potential average daily dose (*e.g.*, mg/kg BW-d)

FIR = Food ingestion rate (prey and/or vegetation) (kg/d)

$C_{diet(i)}$ = Concentration of COPECs in dietary item (i) (mg/kg)

IR_{soil} = Amount of soil ingested (kg/d)

C_{soil} = Concentration of COPECs in soil (mg/kg)

AF_{soil} = Absorbed fraction of COPECs from soil

IR_{sed} = Amount of sediment ingested (kg/d)

C_{sed} = Concentration of COPECs in sediment (mg/kg)

AF_{sed} = Absorbed fraction of COPECs from sediment

AUF = Area use factor (unitless) (foraging area/site area)

BW = Body weight (kg)

Behavioral, spatial and temporal factors that can modify exposure of a receptor will be addressed through the use of an area use factor (AUF) in the generalized exposure model. These are species specific factors that take into account the behavioral (e.g. home range), spatial (size and configuration of the site) and temporal factors (e.g. migration) that can result in discontinuous exposure durations. The area use factor typically ranges from 0 where the receptor spends no time foraging on the site to 1 where the receptor forages 100% of the time on the site. The AUF for each receptor will be determined based on its life history, behavioral patterns, presence of suitable habitat, and availability of site specific information on receptor foraging ranges.

In addition, an absorbed fraction value will be included in the exposure model for soil and sediments to account for the fraction of the oral dose that is absorbed through the gastrointestinal tract. The absorbed fraction values will be determined from the scientific literature or from site-specific data for each class of

COPECs and for soil and sediment concentration data. This absorption factor is especially important for incidental ingestion of sediments and soils since it has been shown that sorption of COPECs to soil may substantially reduce its bioavailability (Alexander, 2000; Menzie, *et. al*., 2000). For food items, it will be assumed that the bioavailability of COPECs from biota and vegetation collected from the site is similar to that observed in laboratory studies. As a result, no adjustment will be made for the biotic portion of the exposure model.

5.1.2 Receptor Tissue Exposure Approach

In addition to the dietary-based approach, exposure of some of the receptors will be evaluated based on concentrations of residues in receptor tissues. Such an approach is presumably a more accurate measure of exposure since assumptions of area use factor, foraging range, dietary composition, and bioavailability are inherently accounted for when one measures concentrations of residues in the tissues of a receptor. Furthermore, since receptors integrate their exposure over a given area of river or floodplain, concentrations of residues in receptor tissues more accurately reflect exposures over an area that corresponds to their foraging range. This approach reduces the uncertainty in an exposure evaluation as compared to an approach based only on an evaluation of concentrations of COPECs in soils and sediments due to the heterogeneity of COPEC concentrations in such media. Receptor tissues that will be collected are discussed in the receptor-specific study plans (Appendices C - G). The exposure that is calculated from this receptor tissue residue-based approach can then be compared to residue-based toxicity reference values (TRVs) (refer to section 5.2.1.2 on tissue residue based toxicity reference values).

5.1.3 Exposure Point Concentrations

Exposure point concentrations (EPCs) for avian and mammalian wildlife will be presented in the BERA for both foodweb items and receptor tissues. USEPA ERA guidance provides for the determination of EPCs and states that the use of upper percentiles or maximum concentrations is appropriate when conducting a screening-level assessment and/or when insufficient data are available to adequately characterize the site. However, in a BERA, guidance recommends the use of both a measure of central tendency and an upper percentile exposure point concentration or a distribution of concentrations. Statistical evaluation of data, including an evaluation of the normality of the data, will be used to determine the most appropriate summary statistics for each data set. For normally distributed data, the arithmetic mean and 95% upper confidence limit (UCL) of the arithmetic mean will be utilized as EPCs. For environmental concentration data that are lognormally distributed (as is the case with most environmental data), a geometric mean and 95% UCL of the geometric mean may be a more appropriate statistic to represent the central tendency of the data. Additionally, the geometric mean is less sensitive to a single elevated value in a data set than the arithmetic mean.

The lower food web data collected within proposed sampling grids, both terrestrial and aquatic, will be used to develop EPCs and grid-specific bioaccumulation factors from soils and sediments. The grid-specific bioaccumulation factors will be applied to comparable habitats within the study area based on COPEC concentrations in soil and sediment samples from the nature and extent investigations. In this way, exposures (and risks) can be estimated for a given receptor (e.g., great horned owls) in a way that includes areas for which food web data are not available. The target number of samples to be collected at the proposed sampling grids are presented in Table 5-1. These target sample numbers are not designed to be sufficient to do statistical comparisons between sampling locations within the area of concern. However, preliminary results indicate that these sample sizes will likely be sufficient for statistical comparisons between sampling grids in the area of concern and those in the reference areas. As analytical results become available, data gaps will be identified and further sampling will be conducted where necessary.

Table 5-1. Target number and type of samples for the exposure pathway analysis.

Matrix	# of Locations[A]	# of Samples Per Sampling Event	# Sampling Event(s)	Total # of Samples
Sediments	6	1 composite	2	12
Aquatic macrophytes	6	1 composite	2	12
Benthic invertebrates	6	3 composites separated by orders	2	36
Crayfish	6	1 composite	2	12
Aquatic emergent insects	6	3 composites separated by orders	2	36
Fish	3	6	1	18
Forage fish	6	1 composite (500 g)	2[B]	12
Floodplain soils	6	1 composite	2	12
Depurated earthworms	6	1 composite	2	12
Non-depurated earthworms	6	1 composite	2	12
Frogs	6	1 composite by species	2	12
Terrestrial macrophytes (consumable leaves)	6	1 composite by species	2	12
Terrestrial macrophytes (fruiting bodies)	6	1 composite by species	2	12
Terrestrial invertebrates	6	3 composites separated by orders	2	36
Small mammals	6	12	2	144

[A] The sampling locations include Sanford, Chippewa Nature Center, Smiths Crossing, Tittabawassee Township Park, Freeland Festival Park, and Imerman Park.

[B] Number of sampling events may vary based on availability of equipment and dietary analyses of great blue herons

5.1.4 Uncertainties

Uncertainties in the dietary-based approach are mostly due to either limited data on dietary composition and concentrations in dietary items. For example, exposure assessments that are based on only one dietary item are likely to be more uncertain than assessments that incorporate data for more of the dietary items that a receptor is known to consume. Uncertainties in the tissue residue-based approach are due to several factors, including limitations in sample size and knowledge as to the amount of time each receptor actually spends on the site feeding. Uncertainties in the exposure assessment will be discussed in the BERA.

5.2 Effects Assessment

The purpose of the effects assessment phase is to summarize available toxicological data, establish toxicity reference values (TRVs) and benchmarks for COPECs for the ERA, and present ecologically relevant field observations. The availability of both dietary exposure and tissue residue-based toxicological data will be evaluated for COPECs and the limitations of these toxicity data discussed. This information will be utilized with exposure data and other field observations to conduct the risk characterization (Section 6.0).

5.2.1 Development of Toxicity Reference Values

A TRV is a concentration of a chemical in water, food, or tissues of a receptor below which toxicological effects are not expected. Ideally, TRVs are derived from chronic toxicity studies in which a dose-response relationship has been observed for ecologically-relevant endpoint(s) in the species of concern, or a closely related species. Specifically, some of the ideal characteristics of high quality toxicity studies that can be used to derive TRVs include:

1. Relatedness of the test species to the receptor of concern;
2. Chronic duration of exposure including sensitive life stages to evaluate potential developmental and reproductive effects;
3. Measurement of ecologically relevant endpoints; and
4. Minimal impact of co-contaminants.

In regards to the relatedness of the test species and the receptor of concern, there is a wide range of species sensitivities to COPECs, especially to TCDD and other Ah receptor (AhR)-active chemicals (Gasiewicz et al. 1991). Thus, the less related the test species is relative to the receptor of concern, the more uncertainty is associated with the TRV. Mustelid and gallinaceous species are among the most sensitive mammalian and avian species, respectively, for reproductive and developmental effects of TCDD and related chemicals. Using mink as an example, several studies have been conducted with this species, which make a species uncertainty factor unnecessary. As for exposure duration, acute studies are of little use when trying to establish NOAELs and LOAELs for chronic effects in mink. Similarly, subtle biochemical effects may have little or no relevance to the long-term reproductive success of mink. As for co-contaminants, their presence in test diets can substantially confound the toxicity results relative to a single chemical or class of chemicals. In particular, assignment of causality, which is key to risk assessment, can be problematic when elevated levels of co-contaminants are present. Thus, such studies should be evaluated carefully to determine the potential impact of co-contaminants. Such studies can be very useful and are most appropriate to answer site-specific questions (i.e., mink feeding studies using fish from Saginaw Bay are appropriate to answer questions related to Saginaw Bay but may not be applicable to the Tittabawassee River since the suite of COPECs is likely different between sites). Since few studies were designed to fulfill all of the ideal characteristics of a high quality study that match the needs of an ecological risk assessment, it is sometimes necessary to apply uncertainty factors (discussed later) or to reject a study from further consideration. In either case, the rationale should be clearly documented for applying uncertainty factors or for rejecting a study.

Sources of toxicological data that will be reviewed to develop TRVs include primary peer-reviewed scientific literature, pertinent reviews of TCDD and related chemicals and other COPECs, Oak Ridge National Laboratory report on benchmarks for wildlife, appropriate USEPA reports, and other relevant sources of information. In the ERA, endpoints such as effects on reproductive and developmental toxicity, reduced survival, or growth will be evaluated and used whenever possible.

5.2.1.1 Dietary-Based TRVs

While ecological receptors can be exposed to COPECs through ingestion, dermal, and inhalation exposure pathways, the predominant exposure pathway for bioaccumulative COPECs such as TCDD is typically through ingestion. Thus, a literature search will be conducted to identify studies from which dietary TRVs can be derived. Typically, dietary toxicity studies are conducted by adding known concentrations of COPECs to the diet. If the body weights and ingestion rates of the test animals are known or can be estimated, then the dietary concentrations can be converted to a daily dose in the units of mg COPEC/kg body weight/d. The resulting TRVs can be compared to site-specific estimates of exposure through the calculation of an ADD_{pot}.

5.2.1.2 Tissue Residue-Based TRVs

In addition to dietary TRVs for COPECs, tissue residue-based TRVs are being used increasingly to evaluate the potential for adverse effects due to bioaccumulative COPECs such as TCDD. For the purposes of the BERA, the term "tissue residue-based TRV" will be synonymous with "maximum allowable tissue concentration (MATC)", a term that is sometimes used by agencies and reported in the literature. In the BERA, tissue residue-based TRVs will be compiled for ecological receptors.

Tissue residue-based TRVs can be compared to site-specific, measurements of tissue concentrations in receptors of concern. When food chain models are used to estimate tissue residues in receptor tissues, caution should be exercised due to the inherent uncertainty associated with such modeling. Some of the uncertainty relating to food chain modeling includes factors such as site foraging frequency, dietary composition, and concentrations of COPECs in dietary items. Tissue residue effect level data are gaining increasing regulatory acceptance as evidenced by the "Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans and Biphenyls in Ecological Risk Assessment" (USEPA 2003).

5.2.1.3 Uncertainty

It is essential to perform a critical evaluation of the applicability of the toxicological data to the site-specific receptors of concern and exposure pathways. TRVs derived in the same species are generally not available for the majority of wildlife receptors and, therefore, it is necessary to derive TRVs using toxicological data for surrogate species in combination with uncertainty factors. Uncertainty concerning interpretation of the toxicity test information among different species, different laboratory endpoints, and differences in experimental design, age of test animals, duration of test, etc., are addressed by applying uncertainty factors (UFs) to the toxicology data to derive the final TRV. For this BERA, general recommendations of Sample et al., (1996), USEPA (1995), and USEPA Region 8 (Henningsen and Hoff, 1997) will be considered for the derivation and use of uncertainty factors. In addition, there is uncertainty concerning the use of WHO TEFs since these are order of magnitude, conservative estimates of relative potency.

5.2.1.3.1 Exposure Duration Extrapolation (UF_A)

This factor is used to estimate the chronic LOAEL or NOAEL dose of a chemical when only acute (short-term) and/or sub-chronic toxicity test data are available. In situations where a chronic NOAEL value for an ecologically relevant endpoint is not available, a chronic NOAEL can be estimated by dividing an acute or subchronic LOAEL by an uncertainty factor that can range between 1 and 10 (USEPA, 1995). In this BERA, NOAEL and LOAEL values will be identified from several toxicological studies on relevant avian and mammalian species. The definition that will be used to identify studies that are classified as chronic exposures for mammalian and avian wildlife is adapted from Sample et al. (1996). In this definition, exposures that occur during critical life stages, such as reproductive and developmental time points, will be considered to represent chronic exposures since these life stages are very sensitive to

adverse effects because of the coordination of multiple pathways of differentiation and proliferation of cells occurring within the embryo.

5.2.1.3.2 Intertaxon Variability Extrapolation (UF_B)

This factor takes into account potential differences in the toxicological sensitivity among species and will be used to estimate an effect concentration or dose for a receptor from laboratory test species and extrapolate these data to the receptor of concern. The magnitude of this uncertainty factor can range from 1 to 10 and will be based on available toxicological data concerning the physiochemical, toxicokinetic, and toxicodynamic properties of the chemical. In addition, the magnitude of the uncertainty factor will also be based on the relatedness of the surrogate species to the receptor being evaluated in the BERA. For example, in the case of mink toxicological studies with TCDD are available for mink as the test species such that a direct comparison can be made. In this instance, an intertaxon variability extrapolation for mink would not be necessary.

5.2.1.3.3 Toxicological Endpoint Extrapolation (UF_C)

This factor is used to estimate a NOAEL from a study when only a LOAEL is available for endpoints that are ecologically relevant for this BERA. In a situation, a NOAEL is derived by dividing a LOAEL by an uncertainty factor that can range from 1 to 10 (USEPA 1995). The size of the UF will depend on several factors including the availability of dose-response information from the study as well as the magnitude of the response at concentrations for which effect were noted. However, an effort will be made to identify studies for which ecologically relevant endpoints were assessed.

After consideration of the available data and necessary uncertainty factors, the TRV is calculated using the equation:

$$TRV = \frac{\text{Study Dose}}{(UF_A * UF_B * UF_C)} \qquad \textbf{Eq. 5-2}$$

5.2.2 Evaluation of Productivity Data and Other Field-Determined Effects Data

Site-specific measures of productivity and other field-effects data for the receptors of concern provide a direct assessment of the effects of COPECs on receptor species inhabiting the study Site. In the multiple-lines-of-evidence approach taken in this BERA, productivity data are a third data set, in conjunction with the dietary-based and tissue concentration-based exposure assessments, which will be used to assess risk of COPECs toward receptors of concern. Unlike both the dietary-based and tissue concentration-based exposure assessments, site-specific measures of receptor productivity directly assess the effects of COPECs on receptor species, and therefore, the uncertainties associated with exposure estimations and comparisons to TRVs are eliminated. Site-specific measures of productivity, if they are adjusted for habitat suitability and other interfering factors, are therefore the most realistic estimations of the COPEC-associated risks that are posed to receptor species inhabiting the study site. Although the ATL study plans include measures of productivity and reproductive health, all the data may not be available for this BERA (Table 1-1).

6.0 BASELINE ERA RISK CHARACTERIZATION PHASE

In this section, approaches to characterize risk will be presented. In brief, risks will be estimated in the BERA through integration of exposure and stressor-response profiles, and risks will be described by discussing lines of evidence and determining ecological adversity. The measurement results are evaluated to determine whether they support a conclusion of no significant risk for each assessment endpoint. In some cases, more than a single measurement will have been conducted to evaluate an assessment endpoint. If the results of those measurements do not agree, those results will be considered in combination, and a conclusion will be based on multiple lines-of-evidence.

6.1 Risk Estimation

6.1.1 Hazard Quotient or Toxicity Quotient Method

The basic approach for most assessment endpoints in the BERA will be a hazard quotient (HQ) approach. HQ values will be calculated for each species under different exposure scenarios and contaminant concentrations in prey by the use of equation 6-1 for comparison to benchmarks or criteria, equation 6-2 for tissue residue data, and equation 6-3 for dietary exposure.

$$HQ = \frac{\text{Exposure (mg/kg)}}{\text{Benchmark or screening value (mg/kg)}} \qquad \textbf{Eq. 6-1}$$

$$HQ = \frac{\text{Tissue concentration (mg/kg)}}{\text{Toxicity reference value (mg/kg)}} \qquad \textbf{Eq. 6-2}$$

$$HQ = \frac{\text{ADDpot (mg/kg - d)}}{\text{Toxicity reference value (mg/kg - d)}} \qquad \textbf{Eq. 6-3}$$

The calculation of a HQ assumes that there is a threshold exposure below which it is unlikely that adverse effects will occur in a receptor population. Due to the conservativeness of the exposure calculations, benchmarks, and TRVs, HQ values less than 1.0 indicate that unacceptable risks are not likely to occur. Conversely, HQ values greater than 1.0 do not necessarily indicate the presence of unacceptable risk, rather they indicate that the potential for unacceptable risk cannot be ruled out and further evaluation is needed. HQ values are not statistical probabilities of adverse effects, rather they are indicators of the level of concern regarding potentially unacceptable effects of chemical exposure to targeted populations. Furthermore, it is important to emphasize that the level of concern for HQ values does not increase linearly once they exceed unity (USEPA 1997). In those instances where HQ values are greater than one, additional lines of evidence will be examined to ascertain the magnitude and extent of any effect on a receptor. While the screening-level ERA does not attempt to quantify the nature and extent of potential risks, results from the BERA will attempt to quantitatively and qualitatively describe the risks to the environment to the extent possible.

ERA guidance (USEPA 1997 and 1998) recommends that when the hazard quotient approach is utilized for characterizing risk to wildlife, that HQs are derived for both the lowest observable adverse effect level

(LOAEL) and the no observable adverse effect level (NOAEL). Furthermore, the following guidelines provide a framework to characterize risk using NOAEL- and LOAEL-based HQs:

- When the site exposure (dose) exceeds the LOAEL and the LOAEL-based HQ is greater than 1.0, the potential for unacceptable risk cannot be rulled out and further evaluation is necessary.
- When the site exposure (dose) is less than the NOAEL and the NOAEL-based HQ is less than 1.0, the risk assessor may reasonably conclude that the quotient evaluation method does not provide evidence of potential risk.
- When the site exposure (dose) is greater than the NOAEL but less than the LOAEL, a definitive conclusion may not be reached based on the predictive method alone. As a result, additional assessment effort in cooperation with the risk manager will be necessary to determine whether there is the potential for unacceptable risk associated with exposure to the COPEC(s).

6.1.2 Probabilistic ERA Approaches

In addition to the stochastic HQ approach, probabilistic risk assessment, incorporating probability distribution function data on key exposure and effect parameters, may be used to assess potential risk of site-related COPECs to ecological receptors.

6.2 Uncertainty Approaches

There are several sources of uncertainties associated with risk characterization estimates that can result in under- or overestimation of risks for receptors at the site. First, there is uncertainty associated with the initial selection of COPECs based on sampling data and available toxicity information. There are also uncertainties associated with the conceptual model used as a basis to investigate the site, since the development of a conceptual model relies greatly on professional judgments and assumptions. In addition, when estimating exposures to receptors of concern, assumptions such as ingestion rates, bioavailability, and area use factors add uncertainty to the exposure estimate. Finally, there are uncertainties associated with effect assessments when exposure data for receptors of concern are compared to literature-derived TRVs that are derived from surrogate species. Differences in study design, duration, and species studied add uncertainty to the effects assessment. Sources of uncertainty will be tracked and discussed throughout the risk assessment process.

6.3 Scientific Management Decision Point #4

Following the risk characterization phase of the BERA, all available data from the multiple-lines-of-evidence approach will be evaluated in consultation with MDEQ to characterize ecological risk at the Site.

7.0 SCHEDULE AND REPORTING

7.1 Schedule

Once MDEQ provides comments on the draft BERA work plan, Dow and ENTRIX will respond to comments and prepare a revised BERA work plan within 60 days. Following approval of the BERA workplan and once consensus has been reached for scientific management decision points (SMDPs) #1 (section 2.2), #2 (section 3.7), #3 (section 4.6), and #4 (section 6.3), Dow and ENTRIX will submit a draft BERA report within 365 days. Once MDEQ provides comments on the draft BERA report, Dow and ENTRIX will respond to comments and prepare a revised BERA report within 60 days.

7.2 Reporting

If any major deviations from the approved Work Plan are necessary because of unanticipated field conditions, the MDEQ (and MDNR and USFWS, if appropriate) will be notified as soon as possible for approval and modification of the Work Plan, if needed. In addition, bimonthly progress reports will be provided to MDEQ beginning after approval of this Work Plan.

Reports from this project will include data obtained from the field and laboratory phases of the study. At the termination of the study, MDEQ will be provided with an electronic copy of both laboratory and field data packages. For a detailed list of items that will be included in data packages refer to section 4.5.2.

The major reports that will be prepared and submitted are listed in Table 7-1. The results of the MSU studies will also be published in scientific peer-reviewed literature in order to provide useful data for health professionals, risk assessors and individuals interested in this information.

Table 7-1. Major reports to be submitted as part of the BERA

Report	Contents
BERA Report	• COPEC concentrations in soils, sediments, and lower food web organisms, • Estimates of exposure to receptors of concern, • Hazard quotient calculations of risk based on dietary-based exposure estimates and toxicity reference values. • COPEC concentrations in tissues of receptor species where available, • Hazard quotient calculations of risk based on receptor tissue concentration-based exposure estimates and toxicity reference values where data is available, • Productivity data for receptors of concern where data are available, • Risk characterization based on multiple lines of evidence.

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Appendix A. Quality Assurance Project Plan (QAPP)

Appendix B. Site Specific Health and Safety Plan (S-HASP)

Appendix H. Standard Operating Procedures (SOP)

TR203r1	Homogenization of Tissue Samples
TR210r1	Extraction and Analysis of PCBs and Non-ortho Coplanar PCBs in Biological and Environmental Matrices
TR211r1	Mono-and-Non *ortho* PCB Analysis by GC-MSD using Chrompack CP SIL 5/C18
TR212r1	Glassware Cleaning: General and Trace Organic Analysis
TR213r1	Extraction and Analysis of 2,3,7,8 Substituted Polychlorinated dibenzo-p-dioxin (PCDD) and dibenzofurans (PCDF) in Sediment & Biota Samples Using the High Resolution Gas Chromatography High Resolution Mass Spectrometry
TR214r1	Documentation, Preservation, Handling, And Tracking of Samples For Analysis
TR220r1	Standard Method for Field Collection of Soils for Chemical Analyses
TR221r1	Standard Method for Field Collection of Sediments for Chemical Analyses
TR222r1	Protocol for Sampling the Edible Portions of Aquatic Vegetation
TR223r1	Protocol for Freshwater Benthic Invertebrate Sampling and Analysis (for the Separate Collection and Analysis of Sediment Associated and Surface Mobile Species)
TR224r1	Protocol for Emergent Aquatic Insect Sampling and Analysis
TR225r1	Protocol for Fish Sampling
TR226r1	Protocol for Terrestrial Invertebrate Sampling and Analysis
TR227r1	Protocol for Sampling the Edible Portions of Terrestrial Vegetation (Fruiting Bodies, Seeds and Consumable Leaves)
TR228r1	Protocol for Terrestrial Small Mammal Sampling and Analysis
TR240r1	Mink Habitat Suitability
TR241r1	Trappers Kit
TR242r1	Dietary Analysis of Scat and Stomach Contents
TR243r1	Track Board Surveys for Mink Abundance Estimation
TR244r1	Placental Scar Identification
TR246r1	Protocol for Conducting Field Sign Surveys of Mink Scat and Tracks during the Summer and Winter
TR247r1	Field Survey of Mink Trapping Pressure
TR248r1	Mink Tooth Extraction and Cleaning for Cementum Aging
TR249r1	Dissection of Mink Carcasses
TR262r1	Protocol for Monitoring and Collection of Box-Nesting Passerine Birds
TR264r1	Protocol for Bird Necropsy, Egg and Shell Examination, and Tissue Archive
TR265r1	Protocol for belted Kingfisher (Ceryle alcyon) Monitoring and Tissue Collection
TR266r1	Great Blue Heron (Ardea herodias) Adult Handling, Banding, and Collection of Blood
TR267r1	Great blue heron (Ardea herodias) Nest Monitoring and Egg and Nestling Tissue Collection
TR270r1	Bald Eagle Observation, Prey Remains Analysis, and Collection of Addled Eggs and Eggshell Fragments
TR271r1	Bald Eagle Nestling Handling, Banding, and Collection of Blood
TR272r1	Great Horned Owls- Location of Natural Nests, Hooting Call Surveys, and Construction and Placement of Artificial Platforms
TR273r1	Great Horned Owl Observation, Prey Remains Analysis, and Collection of Addled Eggs and Eggshell Fragments
TR274r1	Great Horned Owl Nestling Handling, Banding, and Collection of Blood
TR280r1	Protocol for Avian Radio Tagging and Tracking
TR401r1	Sample Management: Receiving, Preservation, Storage, Documentation, Decontamination, and Disposal
TR402r1	Maintenance of Sample Integrity, and Proper Usage of Refrigerators, Freezers, and Liquid Nitrogen Dewars
TR802r1	Data Package Review

Appendix I. Permits in support of MSU study plans